

09/05/00

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09/05/00  
759 U.S. PTO  
09/655232

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: KUME  
Title: METHODS OF USING AN INTRAVASCULAR BALLOON CATHETER IN COMBINATION WITH AN ANGIOSCOPE

Docket No.: SMP0179US02

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate under 37 CFR § 1.10.
- ☒ Request for Continuation Application Under 37 CFR § 1.53(b) with copy of prior application as filed in U.S. Serial No. 08/432,318, filed May 1, 1995, consisting of: Specification (26 pgs. including 5 claims); Abstract (1 pg.); and 6 sheets of drawings; Declaration and Power of Attorney as filed in U.S. Serial No. 08/432,318
- ☒ A Preliminary Amendment (5 pages).
- ☒ An Information Disclosure Statement, PTO-1449 and cited art references (3)
- ☒ A return postcard.
- ☒ **PLEASE CHARGE DEPOSIT ACCOUNT NO. 19-0765 for the required filing fee of \$978.**

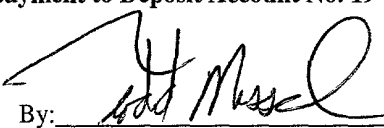
*The Filing Fee has been calculated below as follows:*


**CLAIMS AS FILED**

	No. Filed		No. Extra	Rate	Fee Total
Total Claims:	36	- 20 =	16	x \$18 =	\$288
Independent Claims:	3	- 3 =	0	x \$78 =	\$0
Multiple Dependent Claim Presented:				+ \$260 =	\$0
Basic Fee:					\$690
<b>TOTAL:</b>					<b>\$978</b>

Please charge any additional required fees or credit overpayment to Deposit Account No. 19-0765. A duplicate copy of this sheet is enclosed.

Scimed Life Systems, Inc.  
One Scimed Place, Maple Grove, MN 55311-1566  
(612) 494-2880

By:   
Name: Todd P. Messal  
Reg. No.: 42,883

**CERTIFICATE UNDER 37 C.F.R. § 1.10:**  
"Express Mail" mailing label number: EL056550508US  
Date of Deposit: September 5, 2000  
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, D.C. 20231.  
By:   
Name: Brenda House

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: KUME

Examiner: UNKNOWN  
(in Parent App.: A. NGUYEN)

Serial No. : Unassigned  
(in Parent App.: 08/432,318)

Art Unit: UNKNOWN  
(in Parent App.: 3306)

Filed: Concurrently herewith  
(in Parent App.: MAY 1, 1995)

Docket: SMP0179US02

Title: METHODS OF USING AN INTRAVASCULAR BALLOON CATHETER IN  
COMBINATION WITH AN ANGIOSCOPE

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REQUEST FOR CONTINUATION  
APPLICATION UNDER 37 C.F.R. § 1.53(b)

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Washington, D.C. 20231

Dear Sir:

This is a request for filing a continuation application under 37 C.F.R. § 1.53(b) of prior application Serial No. 08/432,318 filed on May 1, 1995, entitled METHODS OF USING AN INTRAVASCULAR BALLOON CATHETER IN COMBINATION WITH AN ANGIOSCOPE, with the following inventor(s):

1

Full Name of Inventor	Family Name KUME	First Given Name STEWART	Second Given Name M.
Residence & Citizenship	City PLYMOUTH	State or Foreign Country MINNESOTA	Country of Citizenship USA
Post Office Address	Post Office Address 15710 COUNTY RD. 9, #308	City PLYMOUTH	State & Zip Code/Country MINNESOTA 55446/USA

☒ A copy of the prior application as filed is enclosed including a copy of the oath or declaration filed in the parent application.

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

☒ A preliminary amendment is enclosed.

☒ An Information Disclosure Statement, Form 1449 and cited references (3) are enclosed.

The filing fee is calculated on the basis of the claims existing in the prior application including any amendment referred to herein.

**CLAIMS AS FILED**

	No. Filed		No. Extra	Rate	Fee Total
Total Claims:	36	- 20 =	16	x \$18 =	\$288
Independent Claims:	3	- 3 =	0	x \$78 =	\$0
Basic Fee:					\$690
<b>TOTAL:</b>					\$978

☒ Please charge Deposit Account No. 19-0765 for the filing fee of \$978.

The Commissioner is hereby authorized to charge any additional fees as set forth in 37 C.F.R. § 1.16 to § 1.18 or 37 C.F.R. § 1.15(b)(1) which may be required to Deposit Account No. 19-0765.

☒ Amend the specification by inserting before the first line the sentence, "This is a continuation of application Serial No. 08/432,318, filed May 1, 1995, which is a continuation-in-part of application Serial No. 08/200,122, filed February 22, 1994, now issued Patent No. 5,411,016, dated May 2, 1995."

☒ The prior application is assigned of record to Scimed Life Systems, Inc. as recorded at Reel 7473, Frame 0593.

☒ The Power of Attorney in the prior application is to:

Luke Dohmen, Reg. No. 36,783

Peter J. Gafner, Reg. No. 36,517

Todd P. Messal, Reg. No. 42,883

☒ Address all future communications to:

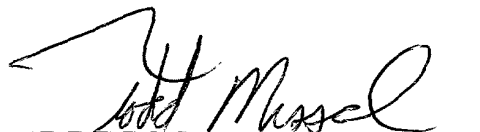
Todd P. Messal, at the address listed below.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statements so made may jeopardize the validity of the application or any patent issuing therefrom.

Respectfully submitted,

Date: 9/5/00



Todd P. Messal, Reg. No. 42,883  
Scimed Life Systems, Inc.  
One Scimed Place, M.S. A150  
Maple Grove, MN 55311-1566  
Telephone: (612) 494-2880

**CERTIFICATE UNDER 37 C.F.R. § 1.10:**

"Express Mail" mailing label number: EL056550508US

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By: Brenda House

Name: Brenda House

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: KUME

Examiner: UNKNOWN  
(in Parent App.: A. NGUYEN)

Serial No. : NEW FILING  
(in Parent App.: 08/432,318)

Art Unit: UNKNOWN  
(in Parent App.: 3306 )

Filed: CONCURRENTLY HEREWITH Docket: SMP0179US02  
(in Parent App.: MAY 1, 1995)

Title: METHODS OF USING AN INTRAVASCULAR BALLOON CATHETER IN  
COMBINATION WITH AN ANGIOSCOPE

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PRELIMINARY AMENDMENT

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Washington, D.C. 20231

Dear Sir:

Prior to examination on the merits, please amend the above-identified Continuation  
Application as follows:

In the Claims

Please cancel original claims 1-5 and add the following new claims 6-42:

6. A marker system comprising:
  - an elongate catheter body;
  - an expandable member attached to a distal end of the catheter body; and
  - opaque markers positioned on the expandable member.
7. The marker system of claim 6 wherein the expandable member is a balloon in fluid communication with the catheter body.
8. The marker system of claim 6 wherein the markers are opaque to light.

9. The marker system of claim 8 wherein the markers are opaque to visible light.
10. The marker system of claim 8 wherein the markers are opaque to infrared light.
11. The marker system of claim 8 wherein the markers are opaque to ultraviolet light.
12. The marker system of claim 6 wherein the opaque markers are arranged in a pattern.
13. The marker system of claim 12 wherein the pattern forms a measuring index.
14. The marker system of claim 13 wherein the measuring index comprises a topographical index.
15. The marker system of claim 6 wherein the opaque markers comprise an ink.
16. The marker system of claim 15 wherein the ink is fluorescent.
17. The marker system of claim 16 wherein the ink is phosphorescent.
18. A balloon catheter comprising:  
an elongate shaft having a lumen therein;  
a balloon attached to a distal end of the shaft and in fluid communication with the  
balloon; and  
a means for marking positioned on the balloon.
19. The means for marking of claim 18 further comprising opaque patterns.
20. The means for marking of claim 18 further comprising patterns which are opaque to light.
21. The means for marking of claim 20 further comprising patterns which are opaque to visible light.

22. The means for marking of claim 20 further comprising patterns which are opaque to infrared light.

23. The means for marking of claim 20 further comprising patterns which are opaque to ultraviolet light.

24. The means for marking of claim 18 further comprising ink.

25. The means for marking of claim 24 wherein the ink is fluorescent.

26. The means for marking of claim 24 wherein the ink is phosphorescent.

27. A method comprising:

inserting a catheter into a human body, the catheter comprising a shaft, a balloon mounted on a distal end of the shaft, and markers on the balloon;

advancing the balloon to a treatment site; and

visualizing the balloon relative to the human body using the markers.

28. The method of claim 27 wherein the step of visualizing the balloon relative to the human body further comprises using light.

29. The method of claim 28 wherein the step of visualizing the balloon relative to the human body further comprises using visible light.

30. The method of claim 28 wherein the step of visualizing the balloon relative to the human body further comprises using fluorescent light.

31. The method of claim 28 wherein the step of visualizing the balloon relative to the human body further comprises using infrared light.

32. The method of claim 28 wherein the step of visualizing the balloon relative to the human body further comprises using ultraviolet light.
33. The method of claim 27 wherein the markers further comprise a pattern of ink.
34. The method of claim 33 wherein the ink is fluorescent.
35. The method of claim 33 wherein the ink is phosphorescent.
36. The method of claim 27 wherein the markers comprise a measuring index.
37. The method of claim 36 further comprising using the measuring index to determine a parameter of the human body or the balloon.
38. The method of claim 37 wherein the parameter is the diameter of the balloon.
39. The method of claim 37 wherein the parameter is the topography of a body vessel.
40. The method of claim 37 wherein the parameter is the geometry of a restriction in a body vessel.
41. The method of claim 27 wherein the step of visualizing the human body further comprises inserting a visualization device into the catheter.



42. The method of claim 41 wherein the visualization device comprises an angioscope.

Respectfully submitted,

Date: 9/5/00



Todd P. Messal, Reg. No. 42,883  
Scimed Life Systems, Inc.  
One Scimed Place, M.S. A150  
Maple Grove, MN 55311-1566  
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BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington,  
D.C. 20231.

By: Brenda House  
Name: Brenda House

-PATENT APPLICATION-

METHODS OF USING AN INTRAVASCULAR BALLOON CATHETER  
IN COMBINATION WITH AN ANGIOSCOPE

005060-225596

By: Stewart Kume

Variable	Mean	Standard Deviation	Minimum	Maximum
Age	34.5	10.2	22	55
Gender	0.5	0.5	0	1
Marital Status	0.7	0.5	0	1
Education	12.5	1.5	10	15
Income	3500	1500	1000	7000
Health	0.8	0.3	0	1
Smoking	0.2	0.4	0	1
Alcohol	0.1	0.3	0	1
Exercise	0.3	0.5	0	1
Stress	0.6	0.4	0	1
Sleep	0.7	0.3	0	1
Diet	0.5	0.5	0	1
Work	0.8	0.3	0	1
Family	0.6	0.4	0	1
Friends	0.7	0.3	0	1
Hobbies	0.5	0.5	0	1
Travel	0.4	0.5	0	1
Volunteering	0.3	0.5	0	1
Religion	0.5	0.5	0	1
Politics	0.5	0.5	0	1
Environment	0.6	0.4	0	1
Technology	0.7	0.3	0	1
Art	0.4	0.5	0	1
Music	0.5	0.5	0	1
Gardening	0.3	0.5	0	1
Fishing	0.2	0.4	0	1
Reading	0.6	0.4	0	1
Writing	0.3	0.5	0	1
Cooking	0.4	0.5	0	1
Cleaning	0.5	0.5	0	1
Shopping	0.6	0.4	0	1
Driving	0.7	0.3	0	1
Traveling	0.5	0.5	0	1
Volunteering	0.3	0.5	0	1
Religion	0.5	0.5	0	1
Politics	0.5	0.5	0	1
Environment	0.6	0.4	0	1
Technology	0.7	0.3	0	1
Art	0.4	0.5	0	1
Music	0.5	0.5	0	1
Gardening	0.3	0.5	0	1
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Reading	0.6	0.4	0	1
Writing	0.3	0.5	0	1
Cooking	0.4	0.5	0	1
Cleaning	0.5	0.5	0	1
Shopping	0.6	0.4	0	1
Driving	0.7	0.3	0	1
Traveling	0.5	0.5	0	1
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Religion	0.5	0.5	0	1
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Writing	0.3	0.5	0	1
Cooking	0.4	0.5	0	1
Cleaning	0.5	0.5	0	1
Shopping	0.6	0.4	0	1
Driving	0.7	0.3	0	1
Traveling	0.5	0.5	0	1
Volunteering	0.3	0.5	0	1
Religion	0.5	0.5	0	1
Politics	0.5	0.5	0	1
Environment	0.6	0.4	0	1
Technology	0.7	0.3	0	1
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Music	0.5	0.5	0	1
Gardening	0.3	0.5	0	1
Fishing	0.2	0.4	0	1
Reading	0.6	0.4	0	1
Writing	0.3	0.5	0	1
Cooking	0.4	0.5	0	1
Cleaning	0.5	0.5	0	1
Shopping	0.6	0.4	0	1
Driving	0.7	0.3	0	1
Traveling	0.5	0.5	0	1
Volunteering	0.3	0.5	0	1
Religion	0.5	0.5	0	1
Politics	0.5	0.5	0	1
Environment	0.6	0.4	0	1
Technology	0.7	0.3	0	1
Art	0.4	0.5	0	

5        This Application is a continuation-in-part of commonly assigned U.S.  
Patent No. 5,411,016 entitled INTRAVASCULAR BALLOON CATHETER FOR  
USE IN COMBINATION WITH AN ANGIOSCOPE, filed on February 22, 1994,  
serial number 08/200,122.

The present invention generally relates to intravascular devices and methods of use thereof. More specifically, the present invention relates to methods of using balloon angioplasty devices in combination with an angioscope.

A wide variety of devices and techniques have been developed to diagnose and treat vascular diseases. Coronary artery disease (CAD) is a vascular disease in which blood flow to the heart muscle is restricted by abnormal deposits in the coronary arteries. The abnormal deposits deprive portions of the heart muscle of essential oxygenated blood. The wide spread impact of coronary artery disease has stimulated the development of diverse types of therapeutic and diagnostic devices.

-2-

angioplasty balloon catheter. Examples of over-the-wire type balloon catheters are described in commonly assigned U.S. Patents 4,976,690 to Solar, and 5,047,045 to Arney. The balloon catheter is inserted into the body by way of the femoral artery and is navigated to a coronary artery, assisted by a guide catheter and a guide wire. The balloon is positioned across a restriction in the artery and the balloon is subsequently inflated. The inflated balloon compresses the restriction outwardly, thus opening the restriction and restoring blood flow to portions of the heart muscle previously deprived of oxygenated blood.

10 Other minimally invasive techniques have been developed as alternatives to balloon PTCA. For example, atherectomy devices are designed to treat specific types of lesion morphology. Atherectomy, as distinguished from balloon PTCA, removes the abnormal deposit or lesion from the vessel rather than molding or compressing the restriction with a balloon.

15 Other medical devices have been developed for use in combination with balloon PTCA. Balloon expandable stents, for example, are used post-PTCA to prevent a dilated restriction from re-closing. A balloon-expandable stent is delivered to the location of the dilated restriction using a balloon catheter. The stent is mounted in its collapsed position onto a deflated balloon and the  
20 balloon catheter is navigated through the vasculature to the portion of the vessel previously dilated. The balloon is expanded to open the stent causing it to engage the inner wall of the vessel. The balloon is then deflated and the balloon catheter is removed, leaving the stent securely in place across the dilated restriction.

25 PTCA balloon catheters, atherectomy devices, stents as well as several other intravascular devices require some means to visualize the operation of the

devices while inside the body. The most common method of visualization is angiography. Angiography involves the injection of radiopaque contrast fluid into the vessel while simultaneously viewing the subject vessel radiographically. Angiography is limited to viewing the subject vessel in a monochromatic two-dimensional plane with no depth of field. To partially compensate for this limitation, a plurality of planar views can be taken and a three dimensional view can be mentally assimilated. However, this method inherently involves a certain amount of human error and since each view must be taken in sequence, critical time is wasted which may jeopardize the health of the patient. In addition, since angiography is limited to monochromatic views, it is not able to accurately identify the pathology of abnormal deposits within the vessel.

Angioscopes, by contrast, allow the treating physician to view a vessel in a polychromatic two dimensional plane with depth of field. The ability to view in two dimensions with depth of field allows the physician to ascertain the morphology of the vessel and the obstructive material in a more accurate and timely manner. Furthermore, the ability to view in color allows the physician to identify the pathology of the obstructive material (e.g. thrombus, plaque and the like). By utilizing angioscopy, the physician can modify the therapy as a function of the pathology and morphology of the obstructive material in the vessel.

Intravascular angioscopy requires a means to displace optically opaque blood from the field of view. The most common method of displacing opaque fluid utilizes an occluding balloon to block the flow of blood proximal to the portion of the vessel to be viewed. An optically transparent fluid such as saline is then flushed distal of the occluding balloon and the angioscope can then view

through the optically transparent fluid. However, utilizing an occluding balloon deprives portions of the heart of essential oxygenated blood and often results in ischemia and patient discomfort. As such, this method is limited to short intervals typically 30 to 45 seconds. Also, the profile of such occluding  
5 balloon catheters is large because the catheter must provide a large flush lumen in addition to an inflation lumen, a guide wire lumen and an angioscope lumen. It is desirable to minimize the profile for intravascular applications. In addition, some of the prior art devices that utilize this method include integral  
10 angioscopes which are not removable and thus inherently increases the cost of the device.

Another method of displacing optically opaque fluid from the field of view utilizes a fluid displacing balloon. In this method, a balloon is inflated with an optically transparent fluid such as saline and is thereby expanded to come into contact with the interior of the vessel. The angioscope can then view  
15 through the optically transparent fluid. However, the prior art devices that utilize this method include integral angioscopes which are not removable and thus inherently increase the cost of the device. Also, the profile of such occluding balloon catheters is large because the catheter must provide an angioscope lumen in addition to an inflation lumen and a guide wire lumen.  
20 Again, it is desirable to minimize the profile of intravascular devices in order to have access to small diameter vessels.

In addition, prior art intravascular angioscopes do not provide a means to collect quantitative information about the vessel and obstructions within the vessel. Angiography, by contrast, provides some quantitative information but  
25 is limited to measuring dimensions in only one plane. As such, it is desirable to

retain all the benefits of angioscopy and provide a means to gain quantitative information.

Examples of intravascular angioscopes include the device disclosed in U.S. Patent No. 4,470,407 to Hussein. Hussein '407 discloses an endoscopic  
5 device including an elongated tube carrying an expandable balloon on its distal end which displaces opaque fluid such as blood and allows for viewing of the walls of the duct which come into contact with the balloon. In addition, U.S. Patent No. 5,090,959 to Samson et al. discloses an imaging balloon dilation catheter for use in angioplasty. Further, U.S. Patent 5,116,317 to Carson Jr., et al.  
10 discloses a balloon-type catheter with an integral optical system for use in angioplasty.

In general, it is desirable to have an over-the-wire type dilating balloon catheter for use in combination with an angioscope. In particular, it is desirable to be able to manipulate and navigate such a balloon catheter independent of  
15 the angioscope. It is also desirable to be able to exchange a first balloon catheter for a second balloon catheter without wasting the integral angioscope of the first balloon catheter. Additionally, it is desirable to have quick and easy access to the treatment site with the angioscope when the catheter is already in place. It is further desirable to visualize different areas of the treatment site while the  
20 therapy is in progress and to have the ability to quantitatively assess dimensional aspects of the objects being viewed.

Thus, there is a need for a device which satisfies these desirable aspects and overcomes the associated disadvantages of the prior art. The present invention overcomes the disadvantages of the prior art and additionally  
25 provides several inventive features that can be fully appreciated by a review of the following summary and detailed description.

### Summary of the Invention

The present invention may be described as a method of performing a medical procedure comprising the steps of (1) delivering an intravascular stent  
5 into the vasculature of a patient, (2) positioning a balloon catheter in the vasculature such that the inflatable balloon is adjacent the stent, (3) inserting an angioscope into the balloon catheter such that the distal end of the angioscope is adjacent an optically-transparent tube traversing the interior of the balloon, and  
10 (4) visually monitoring the stent before, during or after deploying the intravascular stent. The optically-transparent tube may define a guide wire lumen for use with a guide wire and the angioscope may be inserted into the guide wire lumen. The intravascular stent may be a balloon-expandable stent, a self-expanding stent, or a stent made of a photo-responsive polymer.

### Brief Description of the Drawings

The following drawings are referenced in the text of the detailed description of the invention. Several figures are presented in which like numerals in different figures refer to identical parts.

Figure 1 is a plan view of a preferred embodiment of the present  
20 invention with portions in sectional view.

Figure 2 is a sectional drawing of a preferred embodiment of the distal portion of the catheter of the present invention.

Figure 3 is a cross-sectional view of Figure 1 taken at 3-3.

Figure 4 is a cross-sectional view of Figure 1 taken at 4-4.

25 Figure 5 is a side view of a preferred embodiment of a measuring index for use with the present invention.



Figure 6 is a side view of a second preferred embodiment of a measuring index for use with the present invention.

### Detailed Description of the Invention

5 Referring to Figure 1, a medical system 10 in accordance with the present invention includes an angioscopy system 11 and a balloon catheter 12. The angioscopy system 11 includes an angioscope 19 which includes a plurality of illumination fibers 20 and an imaging bundle 21 with an objective lens at its distal end (not shown). The proximal end of the illumination fibers 20 are  
10 connected to a light source 13. The proximal end of the imaging bundle 21 is connected to a series of image processing subsystems, including focusing optics 14, camera 15, computer 16, video cassette recorder (VCR) 17, and video monitor 18. The light source and the image processing subsystems can be arranged as well known in the art such as shown in U.S. Patent 4,331,132 to  
15 Mukasa, which is herein incorporated by reference. The computer 16 can be used to digitally enhance the image and/or quantitatively process the image in order to determine dimensional aspects of the objects being viewed. The dimensional aspects can be calculated by knowing the total magnification of the focusing optics 14 and the distance from end of the angioscope to the measuring  
20 index 46, 47 on the balloon.

Balloon catheter 12 includes a manifold assembly 22 at its proximal end, a catheter shaft 28 and an inflatable balloon 29 at its distal end. The manifold assembly 12 is preferably made of injection molded polycarbonate, however, those skilled in the art will recognize that alternate materials can be used.

25 The manifold assembly 22 includes a flush port 23 which is adapted to be connected to a pressurized fluid supply such as a syringe filled with saline. The

flush port 23 is in fluid communication with a guide wire lumen 43, best shown in Figure 2, which extends through the catheter shaft 28. Saline can be flushed into flush port 23 prior to using the device so as to remove all air trapped in the guide wire lumen 43. Fluid can also be flushed through flush port 23 during  
5 use of the device to clear away blood and unwanted debris. The flush port 23 can also be used to inject contrast media adjacent to and distal from the treatment site.

The manifold assembly 22 also includes an imaging tube port 24 in combination with a hemostatic seal 25 which are sized to allow the insertion  
10 and removal of angioscope 19 or a guide wire (not shown). In one preferred embodiment of the balloon catheter 12, the guide wire lumen 43 would be dimensioned to accept an .018 diameter guide wire. As such, the guide wire (not shown) would need to be removed to advance the angioscope 19 to the therapy site. However, the guide wire lumen 43 could also be dimensioned to  
15 accept both a guide wire and an imaging tube simultaneously. As a further alternative, an inner tube having two proximal lumens (e.g. a guide wire lumen and an angioscope lumen) which merge into one common lumen distally may be employed. With this arrangement, both the guide wire and the angioscope may be disposed in the proximal end of the catheter, but only one of the two  
20 may be advanced distally. For example, the guide wire may be pulled proximally and the angioscope advanced distally when the angioscope is in use, and visa-versa.

In use, the hemostatic seal 25 is used to seal around either the angioscope 19 or the guide wire (not shown) so as to prevent blood from entering the distal  
25 end of the catheter and exiting out the guide wire port 24. The hemostatic seal

25 also allows for fluid to be flushed into the guide wire lumen 43 about the  
angioscope 19 to clear away blood and unwanted debris.

The manifold assembly 22 also includes a balloon inflation port 26 which  
is in fluid communication with an inflation lumen 42, best shown in figure 2.

- 5 The balloon inflation port 26 is adapted to be connected to a pressurized fluid  
source such as an inflation device that allows for a selective inflation and  
deflation of the inflatable balloon 29.

- The proximal end of the catheter shaft 28 is connected to the manifold  
assembly 22. A strain relief 27 is preferably incorporated to prevent kinking  
10 between the relatively stiff manifold assembly 22 and the relatively flexible  
catheter shaft 28. The strain relief 27 is preferably made of extruded polyolefin  
and is dimensioned to fit over the catheter shaft 28 and into manifold assembly  
22.

- Referring now to Figure 2, the catheter shaft 28 includes an outer tube 30  
15 connected at its proximal end to the manifold assembly 22 and connected at its  
distal end to the proximal balloon waist 36 by means of a suitable adhesive such  
as epoxy or urethane. The outer tube 30 also includes a series of tapers 33 to  
facilitate varying flexibility along the length of the catheter shaft 28. The outer  
tube 30 is preferably made of extruded polyethylene with outer tapers 33  
20 formed by drawing the outer tube 30 through a reduced diameter heated dye.  
The outer tube is preferably approximately 135 cm. long and tapers from  
approximately .0474 - .0522 inches at the proximal end to approximately .031 -  
.047 inches at the distal end. Those skilled in the art will recognize that the  
outer tube 30 can be formed of alternate materials and dimensions conventional  
25 in the art.

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The catheter shaft 28 also includes an inner tube 31 which is connected at its proximal end to the manifold assembly 22 and at its distal end to an optically-transparent tube 35. Junction tube 34 serves to connect the inner tube 31 to the optically-transparent tube 35 by means of a suitable adhesive such as epoxy or urethane. Inner tube 31 also includes a series of tapers 32 which impart varying flexibility along the length of the catheter shaft 28. The inner tube 31 is manufactured in a similar manner as outer tube 30. Inner tube 31 is preferably made of extruded polyethylene and is approximately 137 cm. long. The inner tube tapers from .027 - .029 inches at the proximal end to approximately .023 - .025 inches at the distal end. The inner tube 31 can also be formed of various other materials and dimensions which are conventional in the art. Junction tube 34 is preferably made of a thin-walled polymer tube such as polyimide so as to minimize interference with the inflation lumen 42.

Alternatively, rather than incorporate junction tube 34, the optically transparent tube 35 may incorporate a proximal flared portion (not shown) to connect to the distal end of the inner tube 31 by means of a suitable adhesive. The need for junction tube 34 can also be eliminated by forming the optically transparent tube 35 as an integral continuation of inner tube 31 such that the entire inner tube 31 is formed of an optically transparent material.

The optically-transparent tube 35 is connected at its distal end to the distal balloon waist 40 by means of a suitable adhesive such as epoxy or urethane. The optically-transparent tube 35 is preferably formed of polycarbonate or polymethylpentene but may be formed of any optically-transparent material with a preferable optical index of refraction between approximately 1.3 and 1.6. Those skilled in the art will recognize that any optically-transparent polymer may be used. However, it is preferable to match

the index of refraction of the optically-transparent tube 35 to the index of refraction of the fluid used to inflate the balloon 29.

Radiopaque marker bands 41 are secured to the optically-transparent tube 35 to facilitate radiographic placement of the balloon catheter at the therapy site. The marker bands 41 are preferably aligned with the proximal balloon cone 37 and distal balloon cone 39 so as to not interfere with angioscopic visualization. The marker bands 41 can be made of any suitable material conventional in the art such as gold, platinum or an alloy thereof.

The inflatable balloon 29 may be made of conventional balloon materials such as a polyolefin copolymer. A high temperature balloon 29 material such as polyimide may be used if thermal energy is to be applied to the treatment site. Conventional balloon dimensions may be employed.

Referring now to Figures 3 and 4, angioscope 19 is disposed in the guide wire lumen 43 and includes an imaging bundle 21 and a plurality of illumination fibers 20. The imaging bundle 21 and illumination fibers 20 are substantially as described in U.S. Patent 5,116,317 to Carson, Jr. et al. which is herein incorporated by reference. Those skilled in the art will recognize that other angioscopes be used with the present invention.

To facilitate quantitative analysis of the objects being viewed by the angioscope through the balloon catheter 12, a measuring index may be incorporated on the inflatable balloon 29. The measuring index can then be compared relative to an object or a topography being viewed and precise dimensions can be calculated therefrom. For example, in a first preferred embodiment of the measuring index for use with the present invention as shown in Figure 5, the inflatable balloon 29 may include a series of radial bands 46 spaced apart in equal increments of a known dimension. Either by

visualizing the radial bands 46 on the video monitor 18 or by utilizing the computer 16, the diameter of the balloon 29 can be determined at each radial band position. The radial bands 46 may be formed on the outer surface 45 of the transparent balloon 29 using a permanent ink marker, but other suitable marking means may be employed. The ink should be substantially opaque such that they can be clearly seen with the angioscope. Alternatively, the radial bands 46 can be made of fluorescent ink to enhance visualization. Furthermore, the radial bands 46 can be formed of phosphorescent ink which may negate the need for a light source 13 and illumination fibers 20. The radial bands 46 preferably span the body of the balloon 38 between the proximal balloon cone 37 and the distal balloon cone 39.

As shown in Figure 6, a second preferred embodiment of a measuring index for use with the present invention includes the inflatable balloon 29 with both radial bands 46 and longitudinal bands 47. Both the radial bands 46 and longitudinal bands 47 are spaced equally apart at some known distance. In addition to the diameter calculated from the radial bands 46, the longitudinal bands 47 can be used to calculate the topography of the inflatable balloon 29 which conforms to the vessel when inflated. The longitudinal bands 47 are formed in substantially the same way as radial bands 46.

Referring back to Figures 4, 5 and 6, the inflatable balloon 29 includes inner surface 44 and outer surface 45. The radial bands 46 and the longitudinal bands 47 may be formed on either surface or between the surfaces by means of a laminate. If the bands 46 and 47 are formed on the outer surface, it is necessary that the balloon 29 be formed of an optically transparent material such as a polyolefin copolymer so that the bands are visible. In addition, if objects outside the balloon 29 are to be viewed, it is necessary that the balloon

material be optically transparent so that those objects are visible. A balloon material which is not optically transparent is useful to visualize the inside surface of the balloon 44 which will conform to the topography of the vessel upon inflation of the balloon 29.

5           An alternative embodiment of the balloon catheter 12 is contemplated wherein the balloon dilation element 29 is replaced by an expandable braid. An example of an expandable braid is disclosed in commonly assigned U.S. Patent No. 5,222,971 to Willard et al. which is hereby fully incorporated by reference. In this alternative embodiment, the proximal portion of the expandable braid  
10 includes a polymer coating such that when the braid is expanded in the vascular system, blood is prevented from flowing through the braid. A suitable coating such as an elastomer polymer may be applied to the braid to prevent blood from flowing therethrough. Preferred elastomeric polymers include polyurethane, latex and silicone rubber. The preferred method of application of  
15 the elastomeric polymer is by a dip coating process. Alternatively, the elastomeric polymer may be pre-formed into a sleeve or tube configuration and attached to the exterior of the braid. Thus, the blood field is cleared by effectively occluding the blood vessel with the coated expanded braid and flushing the area with saline. It is also contemplated that the distal end of the  
20 braid may be coated thus reducing back bleed and reducing the amount of saline flush required to clear the field of view. Utilizing a stainless steel or other high temperature material for the braid allows for application of thermal energy to the treatment site. The braid effectively forms a geometric matrix which may be utilized in a similar manner as the measuring index described previously. A  
25 transparent inner tube is connected to the distal end of the braid and an outer tube is connected to the proximal end of the braid. Longitudinal displacement

of the inner tube relative to the outer tube actuates the braid into the expanded and contracted positions. As described in U.S. Patent No. 4,998,539 to Delsanti, which is hereby incorporated by reference, a pull wire may be utilized in place of the inner tube to actuate the braid into the expanded and contracted  
5 positions. Utilizing a pull wire in place of an inner tube may reduce the effective profile of the contracted braid. In addition, using a pull wire in place of an inner tube allows the tip of an angioscope to be deflected without being restricted by the inside diameter of an inner tube. However, if an inner tube is utilized, a prism may be employed to direct optical energy orthogonally to the  
10 longitudinal axis of the catheter.

The medical system 10 may be used for a variety of medical applications. For example, the balloon catheter 12 may be used in conjunction with the angioscopy system 11 to navigate through the vasculature and locate vascular restrictions, to diagnose the pathology and morphology of vascular restrictions,  
15 to visually monitor the progress of a PTCA balloon dilation procedure, to assist in deploying a vascular stent, and to assess the results of a given therapy (e.g. balloon dilation, atherectomy, stent deployment, etc.). Additionally, the medical system 10 may be used to perform medical procedures requiring intravascular delivery of photo-energy such as photo-dynamic therapy, photo-  
20 curable stent delivery, arterial paving, photo-thermal tissue welding, and photo-adhesive tissue welding.

In a PTCA procedure, the balloon catheter 12 may be used in conjunction with the angioscopy system 11 in the following manner. A guide wire (not shown) is navigated through the vasculature to a target site (e.g. restriction).  
25 The balloon catheter 12 is then placed over the guide wire and advanced such that the balloon 29 is placed across the target site. Alternatively, the balloon



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catheter 12 may be placed on the guide wire prior to insertion into the vasculature and then both the guide wire and the balloon catheter 12 may be advanced together as a system to the target site. The balloon catheter 12 and the guide wire may be visualized using conventional angiography methods. Once  
5 the balloon 29 is in the desired position, the guide wire is removed and the angioscope 19 is advanced into guide wire port 24 and through the guide wire lumen 43 until the distal end of the angioscope 19 is located within the balloon 29. Prior to dilation, the inside diameter of the native vessel (i.e. the unrestricted portion of the vascular lumen) may be visualized by inflating the  
10 balloon to a low pressure. The diameter of the native lumen may be correlated to a desirable diameter to which the restriction will be inflated. The balloon 29 may then be inflated to dilate the restriction in the vessel and the progress of the balloon inflation can be monitored by way of the angioscope 19. In addition to dilation, the balloon serves to displace all opaque fluid (blood) so that a clear  
15 image of objects outside the balloon 29 may be obtained through the optically-transparent tube 35, the inflation media (not shown) and the balloon 29.

The medical system 10 can also be used to determine the morphology (i.e. geometry or topography) and pathology (i.e. material characteristics) of a restriction in a vessel. This may be done as an initial step to help determine the  
20 best applicable therapy (e.g. balloon dilation, atherectomy, etc.) or subsequent to therapy to help determine the results thereof. To perform these functions, the balloon may be inflated to a low pressure (e.g. 1 ATM) so as to conform the balloon to the geometry of the restriction within the vessel. The angioscope can then be used to view the interior of the balloon which conforms to the  
25 topography of the restriction in the vessel. The measuring index aids the quantitative analysis of the topography of the restriction. The topography of

the restriction may indicate how the restriction will or did respond to different therapies.

The topography of the restriction may also be monitored as a function of pressure to provide additional useful information. Thus, an initial topography  
5 is measured at a first pressure and a subsequent topography is measured at a second higher pressure to derive a dimensional change in topography as a function of pressure. The dimensional change in topography divided by pressure yields a physical characteristic which is somewhat analogous to an elastic modulus. Several measurements may be taken over a series of inflation  
10 pressures to determine physical characteristics over a wide pressure range. The physical characteristics of the restriction may provide additional indications as to how the restriction will or did respond to different therapies.

The medical system 10 can also be used to deliver, monitor and/or  
deploy an expandable stent. The stent may be a balloon-expandable stent, a  
15 self-expanding stent or a photo-curable stent. The stent may be loaded and delivered to the general target site using angiography and the balloon catheter 12 in the conventional manner. The precise delivery point may be determined utilizing the angioscope system 11. Once positioned, the expansion of the balloon 29 and the corresponding expansion of the stent may be monitored  
20 using the angioscope system 11. Once deployed, the angioscope system 11 may be used to determine if the stent is properly anchored in the desired position. In the event that the angioscope 19 indicates that the stent not properly positioned, deployed or anchored, steps can be taken to correct the defect. Corrective measures may include re-positioning the stent, re-anchoring the stent by  
25 inflating the balloon to a larger diameter, removing the stent and/or deploying an additional stent.

Alternative stent delivery methods may also be employed. For example, a self-expanding stent may be delivered using known delivery methods and the balloon catheter can then be used to secure the self-expanding stent in place. The angioscope may be used to visually monitor the stent during  
5 the process of securing the stent in place.

As stated previously, the medical system 10 may also be used to perform medical procedures requiring intravascular delivery of photo-energy such as photo-dynamic therapy, photo-curable stent delivery, arterial paving, photo-thermal tissue welding, and photo-adhesive tissue welding. The photo-energy  
10 may be delivered by an optical fiber (not shown) disposed in a device generically referred to as a photo-energy delivery device. For example, the photo-energy may be delivered by an optical fiber disposed in the angioscope  
19 adjacent the illumination fibers 20.

Photo-energy emitted from the distal end of the optical fiber may by  
15 diffused or focused on a specific site. For example, a diffusing-tipped fiber may be used to uniformly apply photo-energy to the entire treatment site. Light emitted from the optical fiber may also be directed toward a specific area by means of a prism, a mirror, a lens or a combination thereof. Alternatively, portions of an optical fiber may be masked such that only the unmasked  
20 portions emit photo-energy. The unmasked portions may be in the shape of an annular ring, a semi-circular band or a semi-circular elongate window. Further, a deflectable tip optical fiber may be used to steer and direct photo-energy emitted from the distal tip of the fiber.

Since it may be desirable to transmit radiation from the visible, infrared  
25 (IR) or ultraviolet (UV) regions of the optical spectrum, various photo-energy

sources; inner materials and optical fibers may be utilized. The following examples are not exhaustive but are intended to be illustrative.

Suitable optical fibers for transmitting radiation from the visible spectrum include silicate glass, fused silica and sapphire. In the visible spectrum, suitable materials for the inner tube include optically transparent polycarbonate, PTFE, polyether-block-amide, polymethylpentene, polyethylene, polyimide and polypropylene. Suitable visible photo-energy sources include xenon arc lamps, halogen lamps and lasers (e.g. frequency-doubled Nd:YAG, argon, krypton, tunable dye, helium neon, and diode).

Suitable optical fibers for transmitting IR radiation include low-OH fused silica, fluoride glass (e.g.  $ZrF_4$ ), chalcogenide glass (e.g.  $As_2S_3$ ), and crystalline halides (e.g. thallium halides, silver halides, zinc selenide, potassium chloride, hollow waveguides and sapphire). Suitable materials for the inner tube in the IR spectrum include polyester and polyimide (due to their resistance to high temperatures potentially created by IR radiation). Suitable IR photo-energy sources include lasers (e.g. diode, Er:YAG, Er:YSGG, Nd:YLF, Nd:YAG, Ho:YAG,  $CO_2$ , Ho:YLF, and Ti:Sapphire).

Suitable optical fibers for transmitting UV radiation include fused silica and sapphire. Suitable materials for the inner tube in the UV spectrum include polyethylene, polypropylene, polymethylpentene, PTFE, polycarbonate (unloaded) and polyether-block-amide. Suitable UV photo-energy sources include mercury arc lamps and lasers (e.g. nitrogen, excimer, argon, helium-cadmium, and frequency-quadrupled Nd:YAG)

In addition to transmitting photo-energy through an optical fiber, it may be desirable to receive photo-energy through a fiber. An additional optical fiber may be included in the photo-energy delivery device such that one fiber is used

to deliver energy and one fiber is used to receive energy. Alternatively, an optical fiber may be included in the balloon catheter.

For example, it may be desirable to receive IR radiation through a fiber to radiometrically monitor the temperature of the treatment site. This may be particularly useful when thermal energy is being applied to the treatment site and excessive heating may only be effectively prevented by taking direct temperature measurements of the treatment site. A preferred optical fiber material for receiving IR radiation is silver halide. Other suitable optical fibers which may be used for receiving IR radiation include fluoride glass (e.g.  $ZrF_4$ ), chalcogenide glass (e.g.  $As_2S$ ), crystalline halides (e.g. silver halide), zinc selenide, potassium chloride, hollow waveguides and sapphire. A suitable temperature measurement apparatus is a pyroelectric IR detector such as a HgCdTe photodetector. As with the optical fibers used to deliver photo-energy, the fiber used to receive photo-energy may be made to receive directional (e.g. by masking) or diffuse thermal emissions.

Since IR measurements are surface measurements, it is preferable to not have any IR-absorbing or IR-diffusing materials between the face of the IR-detecting fiber and the inner surface of the balloon whose outer surface is in direct contact with the vessel wall. For example, the inner tube and the inflation medium must not be IR-absorbing nor IR-diffusing materials if the IR-detecting fiber is incorporated into the photo-energy delivery device.

The photo-energy is preferably delivered when the balloon is inflated such that the balloon displaces all blood and photo-energy is transmitted through the optically-transparent tube 35, the inflation media and the balloon 29. Accordingly, the method of delivering of photo-energy is similar to the method of visualizing with the angioscope system 11. In particular, a guide

wire is navigated through the vasculature to a target site. The balloon catheter 12 is then placed over the guide wire and advanced such that the balloon 29 is placed across the target site. Alternatively, the balloon catheter 12 may be placed on the guide wire prior to insertion into the vasculature and then both  
5 the guide wire and the balloon catheter 12 may be advanced together as a system to the target site. The balloon catheter 12 and the guide wire may be visualized using conventional angiography methods. Once the balloon 29 is in the desired position, the guide wire is removed and a photo-energy delivery device is advanced into guide wire port 24 and through the guide wire lumen  
10 43 until the distal end of the device is located within the balloon 29. The balloon 29 may then be inflated to displace all opaque fluid (blood) to establish a clear path to the treatment site. The photo-energy may be used for several different applications such as photo-dynamic therapy, photo-curable stent delivery, arterial paving, photo-thermal tissue welding, and photo-adhesive tissue  
15 welding.

Photo-dynamic therapy is the intravascular delivery of photo-energy (e.g. visible, IR, or UV radiation) to a vascular site to activate a photo-activateable drug located therein. Examples of photo-activateable drugs include 8-Methoxypsoralen, Photofrin, Metatetrahydroxyphenyl-chlorin, Tin  
20 Ethyl Etiopurpurin and Benzoporphyrin Derivative Monoacid. The photo-activateable drugs may be used to inhibit smooth muscle cell proliferation or otherwise inhibit the onset of restenosis. A photo-dynamic therapy procedure may follow the steps outlined above but further include the step of introducing a photo-activateable drug prior to delivering the photo-energy. The photo-  
25 activateable drug may be delivered to the target site by systemic administration,

by utilizing a local infusion catheter or by utilizing a site-specific infusion catheter.

Photo-curable stent delivery is the intravascular delivery of photo-energy (e.g. UV radiation) to cure or harden a polymer sleeve (i.e. a stent) positioned  
5 between the balloon and the vessel wall. This method is fully described in commonly assigned U.S. Patent Application entitled IN-SITU STENT FORMING CATHETER filed December 2, 1993 serial number 08/160,589 which is herein incorporated by reference. A similar procedure referred to as arterial paving involves the delivery of photo-energy (e.g. UV radiation) to cure or  
10 harden a liquid polymer disposed between the balloon and the vessel wall.

Tissue welding involves the intravascular delivery of photo-energy (e.g. visible or IR radiation) to generate and apply thermal energy to the treatment site. Tissue welding is useful for securing vascular flaps or dissections that may result from balloon dilation, atherectomy and other intravascular procedures.  
15 Tissue welding may be accomplished by the application of heat which essentially coagulates the vascular tissues together. Alternatively, tissue welding may be accomplished by applying heat in conjunction with a tissue welding adhesive (e.g. collagen or fibrinogen based adhesive solution) to secure the vascular tissues together. The tissue welding adhesive may be loaded with  
20 a light-absorbing dye such that the adhesive cures when exposed to photo-energy. A tissue welding procedure may follow the steps outlined above and further include the step of applying a tissue welding adhesive to the target site prior to the application of photo-energy. The adhesive may be delivered by injection through a catheter or by a coating placed on the exterior of the balloon.  
25 The balloon 29 may then be inflated to displace all opaque fluid (blood), to hold the vascular flap(s) or dissection in place, and to establish a clear path for the

photo-energy through the optically-transparent tube 35, the inflation media (not shown) and the balloon 29. The photo-energy either coagulates the vascular tissues together, cures the adhesive holding the tissues together, or both.

The catheter of the present invention may also be used in conjunction  
5 with a fluorescence diagnostic system. The vessel under investigation may be illuminated with a UV, violet or blue light (typical light sources include argon, krypton and HeCd lasers). When the tissue is excited by this light, the characteristic luminescence of the tissue can be captured by a single optical fiber (or by an angioscope) for optical processing. Typically, the return signal is  
10 passed through an optical filter or a spectrophotometer to analyze the peaks of the emission spectrum of the tissue sample under investigation. The fluorescent signal usually lies in the visible (orange-red) region of the optical spectrum, so the materials chosen for the inner inflation medium and balloon should be relatively transparent to UV and visible light.

15 Prior art percutaneous fluorescence diagnostic systems may be hindered by the presence of blood between the tip of the optical fiber and the site under investigation. In particular, blood may interfere with the signal either because of the optical absorptive properties of the blood or because of the auto-fluorescence signal of the blood. With the optical fiber positioned in the inner  
20 tube under the balloon while the balloon is inflated against the vessel wall, the presence of blood between the tip of the optical fiber and the site under investigation is minimized or eliminated. Accordingly, the catheter of the present invention provides for a much more reliable signal when used in conjunction with a fluorescence diagnostic system.

25 Other advantages of the present invention can be appreciated with a thorough review of the specification. Workers skilled in the art will recognize



that changes can be made to the embodiments described herein without departing from the spirit or scope of the present invention. Accordingly, the following claims define the scope of the present invention.

WHAT IS CLAIMED IS:

1. A method of performing a medical procedure comprising the steps of:
  - i) providing an intravascular stent;
  - ii) providing a balloon catheter having an inflatable balloon adjacent its distal end and an optically-transparent tube traversing the interior of the inflatable balloon;
  - iii) delivering the intravascular stent into a vascular lumen;
  - iv) positioning the balloon catheter in the vascular lumen such that the inflatable balloon is adjacent the intravascular stent;
  - v) providing an angioscope;
  - vi) inserting the angioscope into the balloon catheter such that the distal end of the angioscope is adjacent the optically-transparent tube; and
  - vii) visually monitoring the intravascular stent before, during or after deploying the intravascular stent.
2. The method of claim 1 wherein the optically-transparent tube defines a guide wire lumen and the angioscope is inserted therethrough.
3. The method of claim 1 wherein the intravascular stent is a balloon-expandable stent.
4. The method of claim 1 wherein the intravascular stent is a self-expanding stent.

5. The method of claim 1 wherein the intravascular stent is made of a photo-responsive polymer.

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### ABSTRACT OF THE DISCLOSURE

A method of performing a medical procedure is disclosed which involves the use of a balloon catheter in combination with an angioscope to monitor an intravascular stent before, during or after deploying the stent.

- 5 Specifically, the method may include the steps of (1) delivering an intravascular stent into the vasculature of a patient, (2) positioning a balloon catheter in the vasculature such that the inflatable balloon is adjacent the stent, (3) inserting an angioscope into the balloon catheter such that the distal end of the angioscope is adjacent an optically-transparent tube traversing the interior of the balloon, and
- 10 (4) visually monitoring the stent before, during or after deploying the intravascular stent. The optically-transparent tube may define a guide wire lumen for use with a guide wire and the angioscope may be inserted into the guide wire lumen. The intravascular stent may be a balloon-expandable stent, a self-expanding stent, or a stent made of a photo-responsive polymer.

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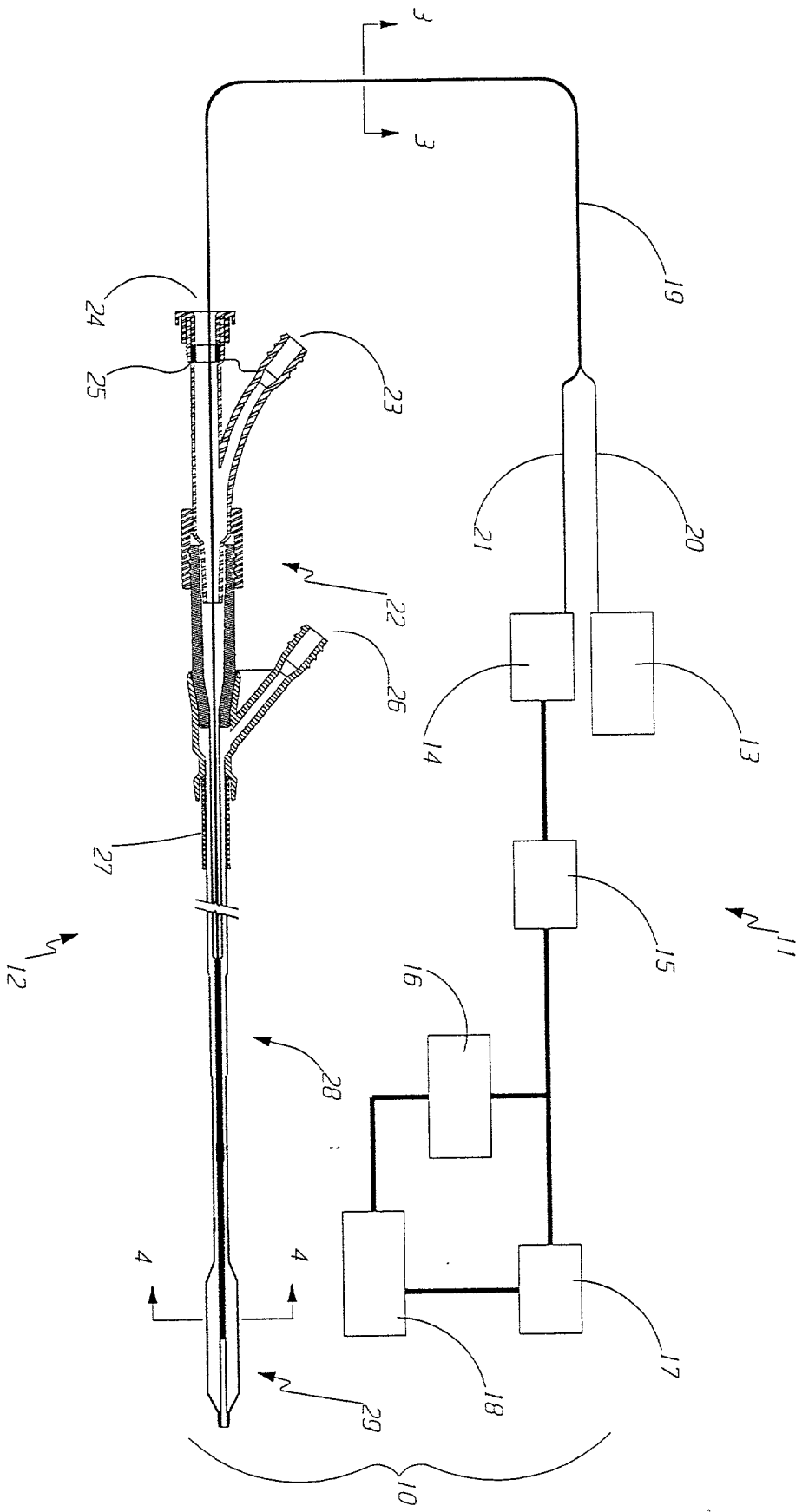


FIGURE 1

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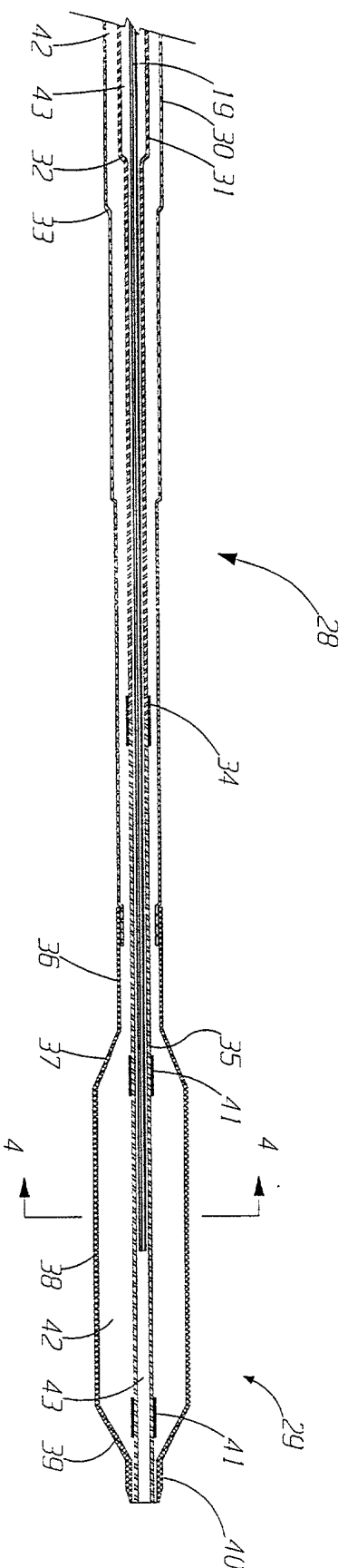


FIGURE 2

	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	2101	2102	2103	2104	2105	2106	2107	2108	2109	2110	2111	2112	2113	2114	2115	2116	2117	2118	2119	2120	2121	2122	2123	2124	2125	2126	2127	2128	2129	2130	2131	2132	2133	2134	2135	2136	2137	2138	2139	2140	2141	2142	2143	2144	2145	2146	2147	2148	2149	2150	2151	2152	2153	2154	2155	2156	2157	2158	2159	2160	2161	2162	2163	2164	2165	2166	2167	2168	2169	2170	2171	2172	2173	2174	2175	2176	2177	2178	2179	2180	2181	2182	2183	2184	2185	2186	2187	2188	2189	2190	2191	2192	2193	2194	2195	2196	2197	2198	2199	2200	2201	2202	2203	2204	2205	2206	2207	2208	2209	2210	2211	2212	2213	2214	2215	2216	2217	2218	2219	2220	2221	2222	2223	2224	2225	2226	2227	2228	2229	2230	2231	2232	2233	2234	2235	2236	2237	2238	2239	2240	2241	2242	2243	2244	2245	2246	2247	2248	2249	2250	2251	2252	2253	2254	2255	2256	2257	2258	2259	2260	2261	2262	2263	2264	2265	2266	2267	2268	2269	2270	2271	2272	2273	2274	2275	2276	2277	2278	2279	2280	2281	2282	2283	2284	2285	2286	2287	2288	2289	2290	2291	2292	2293	2294	2295	2296	2297	2298	2299	2300	2301	2302	2303	2304	2305	2306	2307	2308	2309	2310	2311	2312	2313	2314	2315	2316	2317	2318	2319	2320	2321	2322	2323	2324	2325	2326	2327	2328	2329	2330	2331	2332	2333	2334	2335	2336	2337	2338	2339	2340	2341	2342	2343	2344	2345	2346	2347	2348	2349	2350	2351	2352	2353	2354	2355	2356	2357	2358	2359	2360	2361	2362	2363	2364	2365	2366	2367	2368	2369	2370	2371	2372	2373	2374	2375	2376	2377	2378	2379	2380	2381	2382	2383	2384	2385	2386	2387	2388	2389	2390	2391	2392	2393	2394	2395	2396	2397	2398	2399	2400	2401	2402	2403	2404	2405	2406	2407	2408	2409	2410	2411	2412	2413	2414	2415	2416	2417	2418	2419	2420	2421	2422	2423	2424	2425	2426	2427	2428	2429	2430	2431	2432	2433	2434	2435	2436	2437	2438	2439	2440	2441	2442	2
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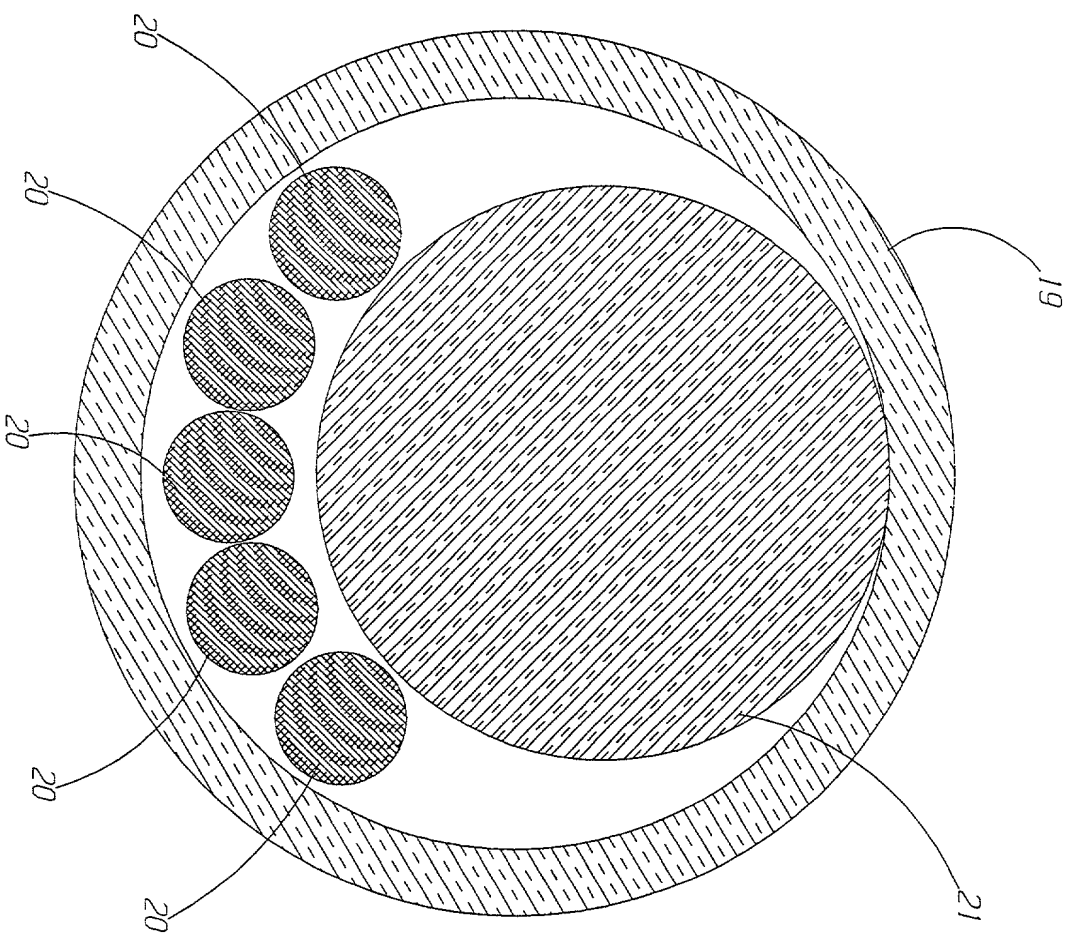
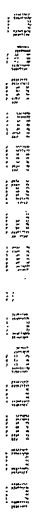


FIGURE 3

09655232-090500



Parameter	Unit	Value	Standard Error	95% CI	P-value
Intercept		1.00	0.00	1.00	0.00
Age	Year	0.02	0.01	-0.01, 0.05	0.15
Gender					
Male		0.01	0.01	-0.01, 0.03	0.45
Female		-0.01	0.01	-0.03, 0.01	0.45
Education	Year	0.01	0.01	-0.01, 0.03	0.35
Income	Year	0.01	0.01	-0.01, 0.03	0.35
Health status					
Good		0.01	0.01	-0.01, 0.03	0.45
Poor		-0.01	0.01	-0.03, 0.01	0.45
Smoking status					
Smoker		0.01	0.01	-0.01, 0.03	0.45
Nonsmoker		-0.01	0.01	-0.03, 0.01	0.45
Alcohol consumption					
Drinker		0.01	0.01	-0.01, 0.03	0.45
Nondrinker		-0.01	0.01	-0.03, 0.01	0.45
Exercise					
Regular		0.01	0.01	-0.01, 0.03	0.45
Irregular		-0.01	0.01	-0.03, 0.01	0.45
Stress					
High		0.01	0.01	-0.01, 0.03	0.45
Low		-0.01	0.01	-0.03, 0.01	0.45
Family size					
Large		0.01	0.01	-0.01, 0.03	0.45
Small		-0.01	0.01	-0.03, 0.01	0.45
Marital status					
Married		0.01	0.01	-0.01, 0.03	0.45
Single		-0.01	0.01	-0.03, 0.01	0.45
Divorced		0.01	0.01	-0.01, 0.03	0.45
Widowed		-0.01	0.01	-0.03, 0.01	0.45
Religion					
Christian		0.01	0.01	-0.01, 0.03	0.45
Muslim		-0.01	0.01	-0.03, 0.01	0.45
Hindu		0.01	0.01	-0.01, 0.03	0.45
Buddhist		-0.01	0.01	-0.03, 0.01	0.45
Other		0.01	0.01	-0.01, 0.03	0.45
Occupation					
Professional		0.01	0.01	-0.01, 0.03	0.45
Managerial		-0.01	0.01	-0.03, 0.01	0.45
Technical		0.01	0.01	-0.01, 0.03	0.45
Skilled		-0.01	0.01	-0.03, 0.01	0.45
Unskilled		0.01	0.01	-0.01, 0.03	0.45
Unemployment					
Employed		0.01	0.01	-0.01, 0.03	0.45
Unemployed		-0.01	0.01	-0.03, 0.01	0.45
Health insurance					
Insured		0.01	0.01	-0.01, 0.03	0.45
Uninsured		-0.01	0.01	-0.03, 0.01	0.45
Healthcare access					
Access		0.01	0.01	-0.01, 0.03	0.45
No access		-0.01	0.01	-0.03, 0.01	0.45
Healthcare cost					
Low		0.01	0.01	-0.01, 0.03	0.45
High		-0.01	0.01	-0.03, 0.01	0.45
Healthcare quality					
Good		0.01	0.01	-0.01, 0.03	0.45
Poor		-0.01	0.01	-0.03, 0.01	0.45
Healthcare satisfaction					
Satisfied		0.01	0.01	-0.01, 0.03	0.45
Dissatisfied		-0.01	0.01	-0.03, 0.01	0.45
Healthcare utilization					
High		0.01	0.01	-0.01, 0.03	0.45
Low		-0.01	0.01	-0.03, 0.01	0.45
Healthcare expenditure					
High		0.01	0.01	-0.01, 0.03	0.45
Low		-0.01	0.01	-0.03, 0.01	0.45
Healthcare equity					
Equitable		0.01			



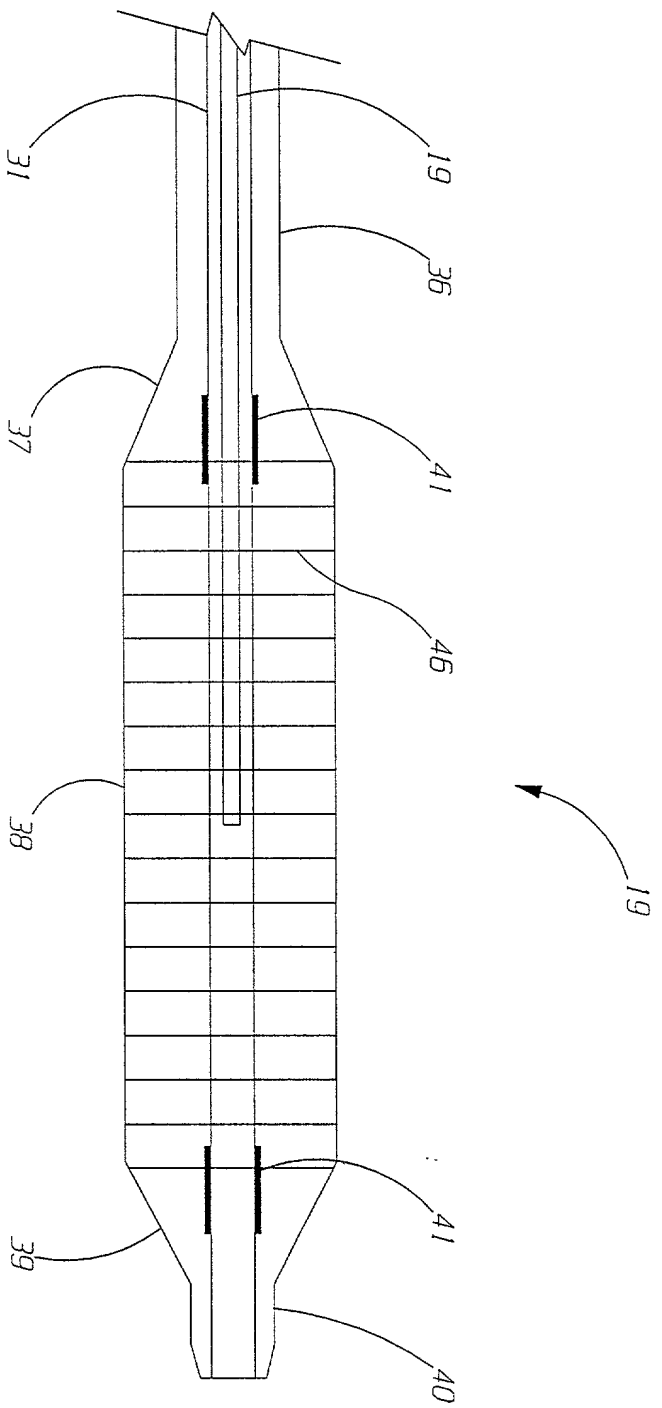


FIGURE 5

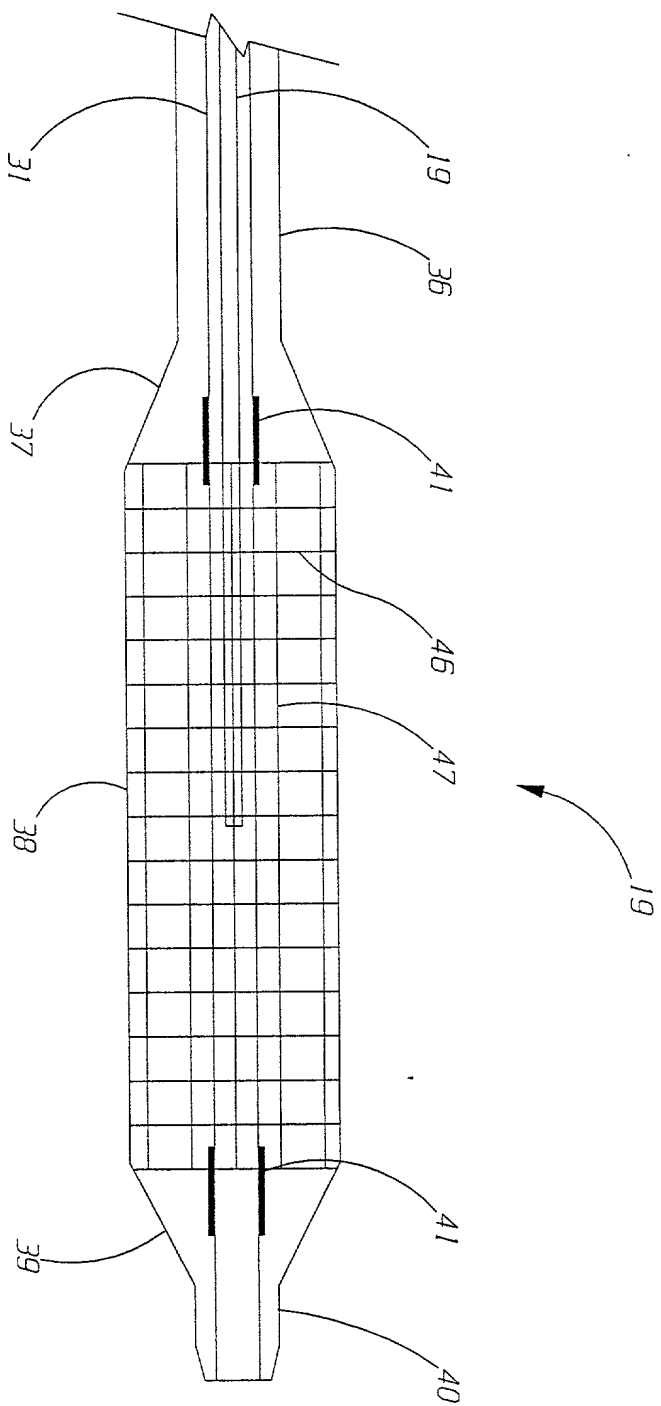


FIGURE 6

	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	2101	2102	2103	2104	2105	2106	2107	2108	2109	2110	2111	2112	2113	2114	2115	2116	2117	2118	2119	2120	2121	2122	2123	2124	2125	2126	2127	2128	2129	2130	2131	2132	2133	2134	2135	2136	2137	2138	2139	2140	2141	2142	2143	2144	2145	2146	2147	2148	2149	2150	2151	2152	2153	2154	2155	2156	2157	2158	2159	2160	2161	2162	2163	2164	2165	2166	2167	2168	2169	2170	2171	2172	2173	2174	2175	2176	2177	2178	2179	2180	2181	2182	2183	2184	2185	2186	2187	2188	2189	2190	2191	2192	2193	2194	2195	2196	2197	2198	2199	2200	2201	2202	2203	2204	2205	2206	2207	2208	2209	2210	2211	2212	2213	2214	2215	2216	2217	2218	2219	2220	2221	2222	2223	2224	2225	2226	2227	2228	2229	2230	2231	2232	2233	2234	2235	2236	2237	2238	2239	2240	2241	2242	2243	2244	2245	2246	2247	2248	2249	2250	2251	2252	2253	2254	2255	2256	2257	2258	2259	2260	2261	2262	2263	2264	2265	2266	2267	2268	2269	2270	2271	2272	2273	2274	2275	2276	2277	2278	2279	2280	2281	2282	2283	2284	2285	2286	2287	2288	2289	2290	2291	2292	2293	2294	2295	2296	2297	2298	2299	2300	2301	2302	2303	2304	2305	2306	2307	2308	2309	2310	2311	2312	2313	2314	2315	2316	2317	2318	2319	2320	2321	2322	2323	2324	2325	2326	2327	2328	2329	2330	2331	2332	2333	2334	2335	2336	2337	2338	2339	2340	2341	2342	2343	2344	2345	2346	2347	2348	2349	2350	2351	2352	2353	2354	2355	2356	2357	2358	2359	2360	2361	2362	2363	2364	2365	2366	2367	2368	2369	2370	2371	2372	2373	2374	2375	2376	2377	2378	2379	2380	2381	2382	2383	2384	2385	2386	2387	2388	2389	2390	2391	2392	2393	2394	2395	2396	2397	2398	2399	2400	2401	2402	2403	2404	2405	2406	2407	2408	2409	2410	2411	2412	2413	2414	2415	2416	2417	2418	2419	2420	2421	2422	2423	2424	2425	2426	2427	2428	2429	2430	2431	2432	2
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# SCIMED Life Systems, Inc.

## United States Patent Application

### COMBINED DECLARATION AND POWER OF ATTORNEY

As a below-named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: METHODS OF USING AN INTRAVASCULAR BALLOON CATHETER IN COMBINATION WITH AN ANGIOSCOPE.

The specification of which

a. X is attached hereto

b. \_\_\_\_\_ was filed on \_\_\_\_\_ as application serial no. \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. \_ filed \_ and as amended on \_\_\_\_\_ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (see page 3 attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. X no such applications have been filed.

b. \_\_\_\_\_ such applications have been filed as follows:

#### FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

#### ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (pending, patented, abandoned)
08/200,122	22/02/94	pending

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Robert E. Atkinson, Reg. No. 36,433;  
Luke Dohmen, Reg. No. 36,783;  
Peter J. Gafner, Reg. No. 36,517;  
John A. Rissman, Reg. No. 33,764

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct SCIMED Life Systems, Inc. to the contrary.

Please direct all correspondence in this case to SCIMED Life Systems, Inc. at the below address:

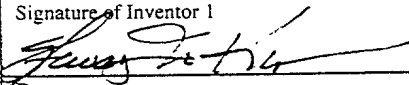
One SCIMED Place  
Mail Stop A150  
Maple Grove, Minnesota 55311-1566  
Attn: Robert E. Atkinson  
(612) 494-2645

I hereby believe that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1	Full Name of Inventor	Family Name Kume	First Given Name Stewart	Second Given Name M.
	Residence & Citizenship	City Plymouth	State or Foreign Country Minnesota	Country of Citizenship U.S.A.
	Post Office Address	Post Office Address 15710 County Rd. 9, #308	City Plymouth	State & Zip Code/Country MN 55446/USA

2	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

3	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

Signature of Inventor 1 	Signature of Inventor 2	Signature of Inventor 3
Date 1 May 1995	Date	Date

For Additional Inventors:  
\_\_\_\_\_ Indicate here and attach sheet with same information, including date and signature.

### § 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor.